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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,455	03/18/2004	Seth A. Foerster	OP-19	5528
21394	7590	09/17/2007		
ARTHROCARE CORPORATION 7500 Rialto Boulevard Building Two, Suite 100 Austin, TX 78735-8532			EXAMINER WOO, JULIAN W	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 09/17/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

intel_prop@arthrocare.com

Office Action Summary

Application No.

10/803,455

Applicant(s)

FOERSTER, SETH A.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/3/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 23-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. That is, with respect to the subject matter of base claim 23, the specification does not describe a first material having a greater tensile strength than the second material.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-6, 8, 10-14, 20-22 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. (4,946,467) in view of Hill et al. (6,045,571). Ohi et al. disclose the invention substantially as claimed. Ohi et al. disclose, in the figures and in col. 3, line 45 to col. 4, line 35, a suture strand with core including a plurality of core fibers made of a fibrous first material (e.g., polyester) and a cover surrounding the core, where the cover is made of a fibrous second material (e.g., silk), where the core fibers are arranged in a twisted bundle, where the cover fibers are arranged to form a woven annular band, where the first material has a high tensile strength material, where the core fibers comprises a bundle of filaments of the first material, where the cover fibers comprises a bundle of filaments of the second material, where each of the core fibers is substantially circular in cross section. However, Ohi et al. do not disclose a first material that comprises a high molecular, high tenacity material or polyethylene; where the second material is a polymeric material selected from the group consisting of PET, polyester, coated urethanes, and mixtures thereof; where the second material is substantially opaque, where the first material is substantially transparent, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. Hill et al. teach, in figures 3 and 3A and in col. 7, line 17 to col. 9, line 15, a first material with a high molecular weight, high tenacity material (e.g., polyolefins according to col. 7, lines 33-38; or polyethylene in blends according to col. 8, line 28-40); a second material that is a polymeric material selected from the group as claimed (e.g., PET), and where each of the cover fibers has

a substantially circular cross section and diameter greater than the diameter of each of the core fibers. It would have been a matter of design choice to choose a first material with a high molecular weight, high tenacity material; a second material that is a polymeric material selected from the group as claimed, and where each of the cover fibers has a substantially circular cross section and diameter greater than the diameter of each of the core fibers. Such choices would be dependent upon the desired size, strength, flexibility, bioabsorbability, and hand for a suture strand. And depending on the choices of materials for the first and second materials, it would be a matter of design choice to apply a substantially opaque or transparent material. The choices would be dependent upon the type material, the thickness of material, and the desired appearance of the suture. In short, it has been held to be within the general skill of a worker in the art to select known materials (whether for the core and/or the cover of a suture strand) on the basis of their suitability for the intended use.

Ohi et al. also do not disclose that the second material has a lower coefficient of friction than the first material. However, Hill et al. teach, in col. 9, lines 31-54 that the second material of the cover is lubricated or coated, or that the second material could be a lubricious polymer (e.g., fluoropolymers). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to lubricate or coat the second material, or apply a lubricious polymer as the second material, so that it has a lower coefficient of friction than the first material of the core. A lower coefficient of friction in the material of the cover would render the suture strand to be more abrasion-resistant as it is being applied for stitching or in an artificial tendon or ligament.

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Moreover, the low-friction filaments of the cover would be enabled to slip over one another when the suture strand is tied into a knot and thereby more evenly distribute any loading between filaments (as taught by patent application 09/159,025, incorporated by reference in Hill et al.).

5. Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. in view of Hill et al., and further in view of Kaplan et al. (5,019,093). Ohi et al. in view of Hill et al. disclose the invention substantially as claimed, but do not disclose that each of the core fibers is substantially wedge-shaped in cross section. Kaplan et al. teach, in figures 7 and 9, core fibers having a substantially wedge-shaped cross section. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kaplan et al, to modify the core fibers of Ohi et al. in view of Hill et al., so that they have a substantially wedge-shaped cross sections. Such a shape would produce a smooth suture strand that would allow resistance-free passage of the suture strand through tissue.

6. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. in view of Hill et al., and further in view of Perciaccante et al. (4,047,533). Ohi et al. in view of Hill et al. disclose the invention substantially as claimed, but do not disclose a core, where a sub-core comprises at least one core fiber and an outer ring comprises a plurality of core fibers. Perciaccante et al. teach, in figures 1 and 2, a suture strand with a core, where a sub-core comprises a single core fiber and an outer ring comprises a plurality of core fibers. It would have been a matter of obvious design choice to modify the suture strand of Ohi et al. in view of Hill et al., so that it has the

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core fiber configuration taught by Perciaccante et al. The choice would be dependent upon the desired strength, flexibility, bioabsorbability, appearance, and hand for a suture strand, where the configuration taught by Perciaccante et al. could give meet the desired demands for achieving good handling characteristics.

7. Claims 23-29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. in view of Hill et al. and further in view of Dunn et al. (4,731,084). Ohi et al. in view of Hill et al. disclose the invention substantially as claimed, but does not disclose that the first, high strength, high tenacity material has a greater tensile strength than the second material. Dunn et al. teach, in col. 4, lines 1-27, a suture strand comprising a core of high strength, high tenacity material (e.g., polyolefins) and having a fiber tensile strength greater than or equal to 50,000 psi, which is greater than the tensile strength of the cover material (C-FLEX, tensile strength of about 2300 psi). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view Dunn et al., to apply a first material in the core of Ohi et al. in view of Hill et al. that has a greater tensile strength than the second material of the cover. Such a first material could withstand the primary loading upon the suture strand with less risk of premature breakage.

8. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohi et al. in view of Hill et al. and Dunn et al., and further in view of Perciaccante et al. (4,047,533). Ohi et al. in view of Hill et al. and Dunn et al. disclose the invention substantially as claimed, but do not disclose a core, where a sub-core comprises at least one core fiber and an outer ring comprises a plurality of core fibers. Perciaccante

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et al. teach, in figures 1 and 2, a suture strand with a core, where a sub-core comprises a single core fiber and an outer ring comprises a plurality of core fibers. It would have been a matter of design choice to modify the suture strand of Ohi et al. in view of Hill et al. and Dunn et al., so that it has the core fiber configuration taught by Perciaccante et al. The choice would be dependent upon the desired strength, flexibility, bioabsorbability, appearance, and hand for a suture strand, where the configuration taught by Perciaccante et al. could give meet the desired demands for achieving good handling characteristics.

Response to Amendment

9. Applicant's arguments with respect to claims 1-33 have been considered but are not persuasive: See the new grounds of rejection above. With respect to the argument that no combination of Ohi and Hill teach a suture comprising a first material of high molecular weight, high tenacity material: The Examiner disagrees, and the rejection points out again, Hill's reference to such a material (i.e., polyolefins). With respect to the argument that Ohi and Hill do not teach a cover material different from the core material: Ohi indeed discloses a core material different a cover material, while Hill teaches various equivalent or substitute materials for the materials disclosed by Ohi, where the materials taught by Hill would obviously be chosen according to the intended use of the suture strand.

With respect to arguments regarding Hill's teachings about core "popout": The Examiner did not consider the teachings about "popout" to be germane to the rejection presented above. That is, only Hill's teachings about materials for a suture strand with

a core and a cover were applied. The Applicant's suggestion that a "core with increased strength may be more likely to popout" is conjecture. Moreover, as the Applicant has pointed out, Hill addresses the problem of core "popout" by varying pick counts, not by addressing materials applied for the core and/or cover.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

September 9, 2007